

## REMARKS

Claims 1-7 and 10-35 are pending in this application. Independent claims 1 and 12 have been amended. Independent claim 20 has been amended to a dependent claim. No new matter has been added. Reconsideration of the claims in view of the following remarks is respectfully requested.

### Comments on Previous Applied References

To expedite prosecution, the Applicants will comment on the previous applied references -- U.S. Patent No. 5,951,492 to Douglas (“Douglas”) and U.S. Application Publication No. 2003/0171696 to Dosmann (“Dosmann”).

Amended claim 1 recites “wherein the second end of the outer end cap and the second end of the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection.” Claim 12 recites “wherein the outer end cap and the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection.” The claimed inner and outer end caps are advantageous as explained in the present invention because the outer end cap contacts a test subject’s skin and the test subject’s skin is pulled against the inner end cap during the lancing operation. See page 3, lines 23-29 of the patent application. Thus, the test subject’s skin is stretched flat against the open end of the inner end cap and “[t]his stretched, flat skin facilitates sample formation and collection.” See page 6, lines 20-22 of the patent application.

Neither Douglas nor Dosmann discloses, teaches or suggest such outer and inner end caps. The Office Action previously equated an inner sleeve 66 in Douglas as disclosing the claimed inner end cap and further stated that the skin contacts the inner sleeve 66 and cites to FIGs. 5 and 6 of Douglas. Page 3 of the Office Action dated April 14, 2009. The differences between Douglas and the present invention may be shown by comparing FIGs. 5 and 6 of Douglas and FIGs. 3 and 4 of the present invention.

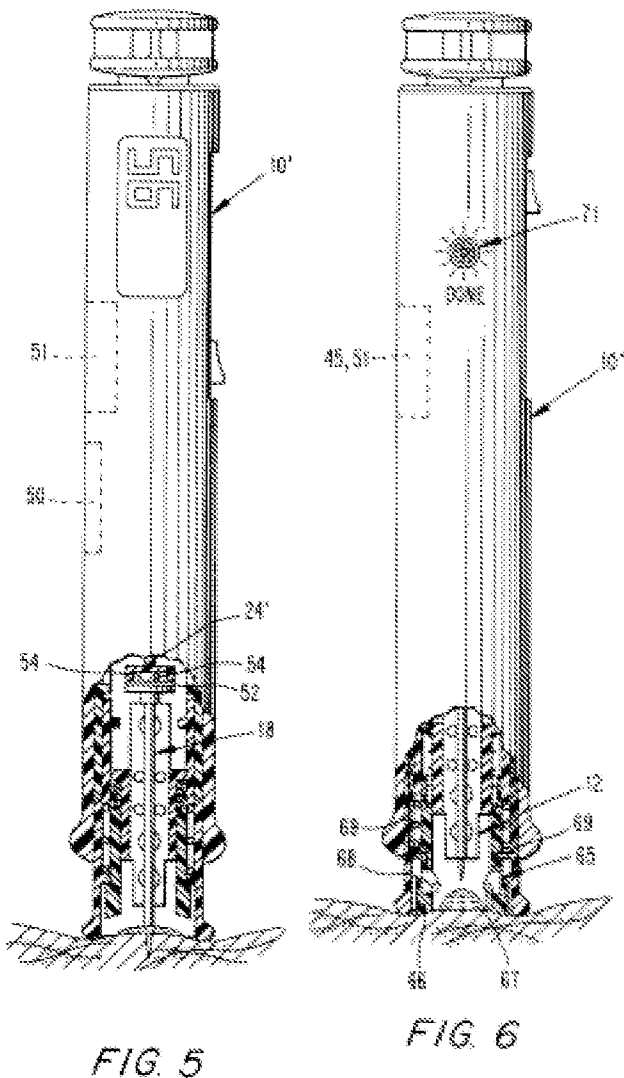


Fig. 3

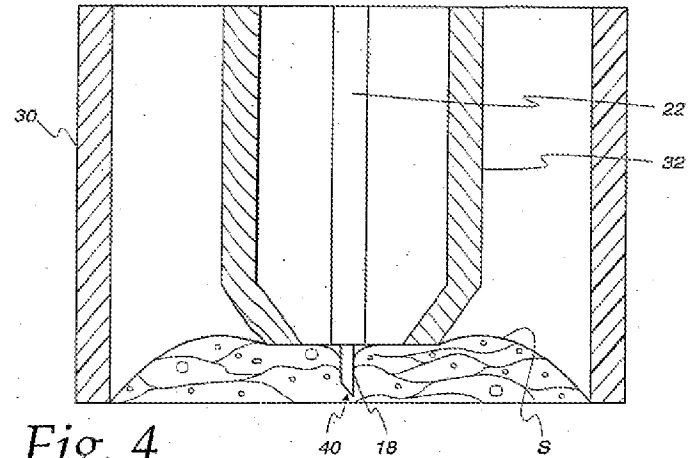
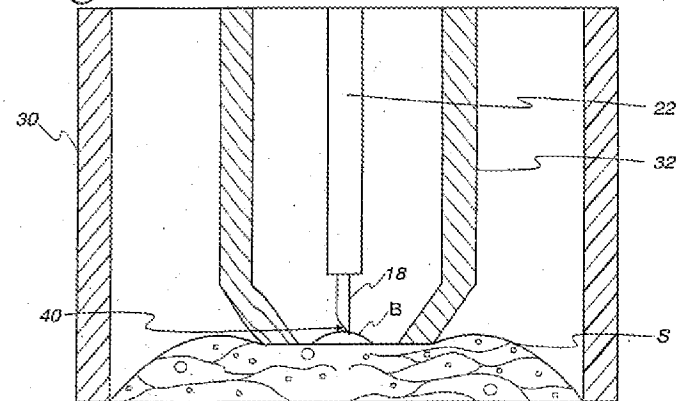


Fig. 4



As shown clearly in FIG. 5 in Douglas, the inner sleeve 66 (not labeled in FIG. 5, but labeled in FIG. 6) does not make (1) “contact with the skin in the lancing position to assist in sample formation and collection” as recited in claim 1 or (2) have “the outer end cap and the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection” as recited in claim 12. Rather, the inner sleeve 66 in Douglas is spaced sufficiently above the skin during lancing as shown in FIG. 5. The other applied referenced (Dosmann) does not disclose, teach or suggest the use of the claimed outer and inner end caps.

Furthermore, as discussed in the prior response, Douglas does not disclose “a hollow lancet having a tip adapted to puncture skin and to collect a body fluid sample, the interior of the hollow lancet forming a channel for moving a fluid sample from the tip to a reaction area” as recited in claim 1, which was acknowledged by the Examiner. Claim 12 also recites the lancing and collection device including a hollow lancet having a tip for puncturing skin.

In an attempt to address the hollow lancet deficiency in Douglas, the Office Action previously applied Dosmann. See page 3-4 of the Office Action. Specifically, the Office Action stated that “it would have been obvious to one of ordinary skill at the time of[] the invention to substitute Douglas’ disposable element comprising separate needle and capillary tube connected to a test element with Dosmann’s singular hollow lancet for lancing the skin and collecting fluid through the interior of the lancet in order to improve test time by integrating the lance, harvest and analysis operation as taught by Dosmann. The Applicants respectfully disagree.

There is no teaching or suggestion to a skilled person to combine Douglas and Dosmann for several reasons. First, the lancing mechanism of Douglas is quite different from that of Dosmann. The lance of Dosmann is unmovable and, thus, has a single position. See par. 10, lines 4-5 of Dosmann; FIG. 1. The housing 18 of Dosmann controls the depth of a puncture into a patient’s skin by the lance 12. Par. 10, lines 4-5. The depth of a puncture corresponds to the length of the lance 12 extending out of the housing 18. Dosmann; Par. 10, 5-7. Douglas, on the other hand, is movable and is adapted to move between retracted and lancing positions. See, e.g., FIGs. 1, 2, 5 and 6.

Second, Dosmann discloses that it is a disposable optical format/integrated lance for lancing the skin. See abstract of Dosmann. Douglas does not disclose a disposable lancing device, but rather only discloses a disposable lancet 12. See col. 6, lines 57-63 of Douglas. The lancing device disclosed in Douglas is reusable after the disposable lancet 12, capillary tube 18 and test strip 30 are discarded. Thus, the devices disclosed in Dosmann and Douglas have different uses – the lance of Dosmann is disposable, while the lancing device of Douglas is reusable.

Thus, in summary, a skilled person would not look to combine the disposable unretracted integrated lance with optical format of Dosmann with the relatively complex lancing mechanism of Douglas.

Therefore, independent claims 1 and 12 are not obvious over Douglas, Dosmann or the combination thereof for at least these reasons. Thus, independent claims 1 and 12 should be in a condition for allowance.

Dependent Claims 2-7, 10, 11 and 13-35

For at least the same reasons as discussed above with respect to independent claim 1, dependent claims 2-7, 10, 11 and 13-35 also are not obvious over Douglas, Dosmann or the combination thereof.

**CONCLUSION**

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Commissioner is authorized to deduct \$360.00 for a second month extension of time, and \$810.00 for the Request For Continued Examination. Please note that the Applicant had previously paid a one-month extension fee of \$130. Should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Nixon Peabody LLP Deposit Account No. 50-4181, Order No. 247082-000090USPX.

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Respectfully submitted,

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